

## REMARKS

The sequence of the claims is now 1-11, 13, 15, 17, 18 and 20. Claims 12, 14, 16 and 19 have been cancelled. Claims 11, 13, 15, 18 and 20 have been amended. Claims 1 – 10 were allowed by the Examiner in the first Office Action and remain unchanged. Claim 17 also remains unchanged. Claims 1-11, 13, 15, 17 - 18 and 20 remain in this application.

No objections are noted to the drawings filed on September 15, 2003.

The one-word change in the Specification (page 14) is intended to correct an obvious typographical error.

The changes made to claims 13, 15 and 20 are necessitated by the changes made to claims 11 and 18 and to be consistent with antecedent language.

Support for the new language in the amended claims (claims 11, 13, 15, 18 and 20) is found on page 5, lines 10-11, page 5, lines 25-27, page 9, lines 13-15, page 11, lines 11-20, page 12, lines 8-14, page 12, lines 18-31, page 13, line 1, page 15, line 31 and page 16, lines 1-3, of the current Specification, as well as in original claims 12, 14, 16 and 19.

No new matter has been introduced in the Specification or in the claims through the new language.

The undersigned attorney wishes to thank Primary Examiner Ivars C. Cintins (Art Unit 1724, Tel. 571-272-1155) for the courtesy of the applicant-initiated telephone conference that took place on November 12, 2004. During that telephone conference, the basis for the current rejection of the system claims (claims 11-20), the cited Harder reference in the context of its applicability to a 35 U.S.C. 102 (b) rejection of systems claims and options for amending the rejected claims so as to structurally differentiate them from the Harder reference and put them in condition for allowance were briefly discussed. No specific agreement on the allowability of the currently rejected claims was discussed. Examiner Cintins will issue an *Interview Summary* office communication in due course summarizing the substance of the November 12, 2004 telephone conference, which will become part of the record of this application.

## **RESPONSE TO EXAMINER'S DETAILED ACTION**

### ***Claims Rejection under 35 USC §102***

See quotation of 35 USC § 102 (b).

The Examiner has rejected claims 11 – 20 under 35 USC § 102 (b) as being anticipated by U.S. Patent No. 4,341,636, of Harder et al., on the basis that Harder et al. discloses a system that comprises the elements recited in Applicant's claims 11 – 20.

Claims 12, 14, 16 and 19. Claims 12, 14, 16 and 19 have been cancelled by this Amendment and are no longer pending.

Claims 11, 13, 16, 17, 18 and 20. Claims 11, 13, 16, 17, 18 and 20 are still pending and rejected. Independent claims 11 and 18, on which claims 13, 16, 17 and 20 depend, have been rewritten by this Amendment and, as discussed below, now include limitations that clearly distinguish them from the prior art.

The Harder et al. reference (U.S. Patent No. 4,341,636) is concerned with a process for the treatment of wastewater. This is not a method for manufacturing ultra pure or pharmaceutical water, but a process for removing heavy metal materials, alkali metal materials and alkali earth metal materials from waste water generated in the manufacture of cadmium-nickel rechargeable batteries and the like. The water is treated so that it may be discharged into a waterway or reused in the battery manufacturing process. This water does not resemble at all the ultra pure water made by the system of applicant's invention. The process of Harder et al. does not have or deal with the problems caused by the presence of chlorine and for that reason Harder et al. do not have, or need, a dechlorinator. As explained on page 3, lines 26-31, page 4, lines 1-13 and page 5, lines 7-11, of applicant's Specification and noted in applicant's claims, the initial presence of chlorine in the water and its subsequent removal by means of a dechlorinator are integral parts of the problem and solution addressed by the system of applicant's invention. The Harder et al. reference does not disclose this problem or offer a solution and, of course, does not have a dechlorinator as part of its process. As now amended, claims 11 and 18 require that (a) the feed water has certain chlorine content, (b) a dechlorinator, not just any carbon filter, is provided, and (c) the dechlorinator is able to change the chlorine content of the water it processes in a specified manner, i.e., it must lower it to less than about 20 ppb. Harder et al. do not have the equipment to do that and, for that reason, the Harder et al. reference does not anticipate claims 11 and 18, which, as now amended, stipulate the type of apparatus needed to do it.

Claims 11 and 18 have also been amended to include structural limitations as suggested by the Examiner in the September 30 Office Action. Thus the means for using the low-pressure steam to sanitize the specific equipment components recited by the claims are now described as a specific arrangement of pipelines provided with specific valves that bring the steam in contact with the surfaces of the equipment being sanitized in a specific manner that accomplishes the sanitization. None of these elements are present or described in the Harder et al. reference. Harder et al. cannot and do not *sanitize* anything with their “evaporation of a portion of the wastewater” (Harder et al. at column 8, lines 55-59) because they do not need to do it and because they simply do not have the equipment capable of doing it. The “evaporation” returned stream flowing through conduit 42 in the process of Harder et al. is simply steam being vented in Harder et al.’s water flow balance tank 121 in order to conserve heat and vent condensables. This is an open tank, open to the atmosphere, and incapable of allowing *sanitization* of any equipment components since it does not provide for or allow the steam to reach any particular temperature and remain in close contact with the local equipment surfaces for a period of time sufficiently long to destroy bacteria or otherwise sanitize anything. The steam here is purposely made to dissipate into the atmosphere, and there is no description or suggestion of valves being incorporated into the system capable of preventing the steam from escaping, keeping it in closed contact with the surfaces of any equipment components and/or maintaining it at any particular temperature for any particular length of time. The system structure required by applicant’s claims 11 and 18, as now amended, is simply not present in Harder et al. Applicant’s system requires that valves be incorporated into the system (connected to the pipelines) and that they (a) bring the steam in close contact with the specified surfaces and (b) keep the steam in close contact (and prevent it from escaping and dissipating) for a specified time and at a specified temperature sufficient to cause the *sanitization* of the mechanical equipment components. Harder et al. do not have the equipment to keep low-pressure steam in close contact for a time and at a temperature sufficient to cause the *sanitization* of the mechanical equipment components and, for that reason, Harder et al. do not anticipate amended claims 11 and 18.

Another reason why neither Harder et al. nor any of the cited prior art anticipates or suggests applicant’s invention is that the structural combination of elements stipulated by the system of applicant’s invention (not just as defined by the elements themselves but also by their specific physical location and sequential order with respect to each other) is not disclosed or suggested by

Harder et al. or by any of the cited prior art. Thus the stipulated location of the still (downstream from the dechlorinator), the stipulated location of the mechanical equipment through which the low-pressure steam must be distributed (subsequent to the point of dechlorination but prior to the location of said still), etc., along with the sequential order of the unit operations, constitute a unique structural combination of elements which is responsible for the successful use of distillation for manufacturing pharmaceutical water in conjunction with the use of chlorination as a means of sanitization, one of the objects of applicant's invention. The unique structural combination of elements disclosed in amended apparatus claims 11 and 18 (as well as in dependent claims 13, 16, 17 and 20) are neither disclosed nor suggested by the prior art and satisfy the structurally differentiating requirements of *Ex parte Masham*, 2 USPQ2nd 1647 (1987). These claims should be allowed.

#### ***Allowable Subject Matter***

Claims 1 –10. The Examiner has allowed claims 1 –10 in the first Office Action. Claims 1-10 remain unamended and allowed in this application.

#### ***Prior Art Made of Record and Not Relied Upon***

Applicant wishes to address the pertinence of the prior art made of record and not relied upon. The Examiner has correctly indicated that U.S. Patent No. 6,679,988, of Gsell, discloses a conventional process for manufacturing pharmaceutical water. While there may be some similarities among certain features of applicant's invention and some of the individual elements disclosed in the Gsell patent, that patent does not disclose or suggest the combination of elements set forth in any of applicant's pending claims as now amended. Gsell does not have the serious biological active constituent problem that applicant has, is able to use reverse osmosis as a means of purification and does not disclose the unique distribution of controlled low-pressure steam throughout the mechanical equipment at the locations specified by the method and system of applicant's invention.

#### ***Conclusion***

Applicant has discovered and now provides new and unobvious combinations of system components, as set forth in amended independent claims 11 and 18, as well as in dependent claims 13, 16, 17 and 20, that allow the heretofore-impracticable sanitization of water

purification equipment to less than 10 colony-forming units per milliliter while manufacturing pharmaceutical water of excellent quality from chlorinated water by distillation and, in doing so, applicant advances the art of commercially produced pharmaceutical water manufacturing. The specific combinations stipulated in amended claims 11 and 18 (as well as in dependent claims 13, 16, 17 and 20) are neither disclosed nor suggested by the prior art, nor are they obvious combinations in the context of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148, USPQ 459 (1966) for determining obviousness under 35 USC § 103 (a). These claims should be allowed. Claims 1 – 10 have already been allowed and remain unamended. Applicant is entitled to receive patent protection for his new method and system for the manufacture of pharmaceutical water as set forth above.

Reconsideration, reexamination and allowance of all of the remaining claims are respectfully requested.

If the Examiner feels that a telephone conference with applicant's attorney will help clarify any issues that may remain in connection with this Office Action, answer any questions or otherwise help expedite the prosecution of this application, he is requested to please call applicant's attorney at a time convenient to the Examiner during regular business hours at the telephone number set forth below. The Examiner is also invited to contact applicant's attorney via electronic mail at the electronic mail address set forth below.

A Certificate of Mailing is attached.

Please enter this Amendment in the record of this patent application and give it favorable consideration. The Commissioner is hereby authorized to charge any deficiency in the payment of any required fee to USPTO Deposit Account No. 501834.

Respectfully submitted,



Raúl V. Fonte  
Attorney for Applicant  
1615 Poydras Street, Suite 253  
New Orleans, Louisiana 70112  
USPTO Reg. No. 27,882  
USPTO Customer No. 26996  
Tel 504-582-4234  
rfonte@cticonsult.com  
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